



CHARLES H. CHEVALIER
Director

Gibbons P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Direct: (973) 598-4611 Fax: (973) 639-6263
cchevalier@gibbonslaw.com

June 27, 2021

VIA ECF

Honorable Michael A. Shipp, U.S.D.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Amgen Inc. v. Sandoz, Inc.*
Civil Action No.: 3:18-cv-11026-MAS-DEA (consolidated)

Dear Judge Shipp:

We, along with Covington & Burling LLP and Sidley Austin LLP, represent Plaintiff Amgen Inc. in the above-referenced matter, regarding an issue relating to the post-trial briefing.

As Your Honor may recall, at the end of trial, Amgen pointed out that Defendants did not address during trial all of the invalidity positions and prior art references raised in Defendants' pre-trial brief.¹ However, it is not clear which positions and arguments they are continuing to advance. Because there are no responsive post-trial briefs, and to make the best use of the parties' and Court's time, by ensuring that both parties were addressing the same issues in post-trial briefing and at closings, Amgen asked Defendants to identify with particularity which invalidity arguments, and more importantly, which references and combinations Defendants intend to use to support those arguments in their post-trial brief. Ex. A (6/24 email from A. Hansen). Defendants confirmed in open court at the end of trial on Friday, June 25, that they would do so.

The response received from Defendants was incomplete. *See* Ex. A (6/26 email from S. Lerner). Defendants identified the general categories of invalidity arguments they intend to make (e.g., "anticipation," "obviousness"), but with respect to the combinations of prior art references, asserted that "the obviousness combinations are apparent from our expert's testimony." *Id.* Defendants' response is incorrect – we would not have asked for clarification if the experts' testimony was, in fact, clear – but, even if it were clear, Defendants are hardly inconvenienced by repeating those facts in an email.

Amgen sought further clarification from Defendants, taking the time to identify what it understood to be the grounds, references, and combinations that Defendants or their experts had

¹ For example, for the '101 Patent, Defendants briefed obviousness combinations based on the '358 Patent. ECF No. 398 at 61–66. Dr. Steed did not address the '358 Patent during his testimony at all. Similarly, for the '536 Patent, Defendants briefed three obviousness combinations, two of which included Takeuchi and WO '606. ECF No. 398 at 38. Neither Dr. Page nor Dr. Gilmore addressed either of those references. Moreover, Muller 1998, which was included in only *one* of Defendants' combinations, *see id.*, was discussed by both Dr. Page and Dr. Gilmore during their discussion regarding the purported obviousness of the asserted claim of the '536 Patent.

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advanced. Ex. A (6/27 email from A. Hansen). Defendants refused to provide any further clarification, instead responding that Amgen's "position [that defendants had not identified their combinations] was absurd" and that they "consider this topic over." Ex. A (6/27 email from M. Rurka).

Defendants bear the burden of proof on the issue of invalidity, and Amgen should not have to use its limited briefing space to address arguments that Defendants raised in their pre-trial brief, but are not intending to advance in their post-trial brief. While we regret the necessity of seeking the Court's intervention because Defendants refused to identify the arguments they intend to brief, the simple fact is that our simultaneously-provided brief will need to respond to Defendants' arguments. To do so, Amgen needs to know what arguments Defendants are raising. Therefore, to ensure that the Court hears from all parties on the same issues in their respective post-trial briefs, we ask this Court to order Defendants to provide, by no later than noon ET on Tuesday, June 29, the invalidity defenses, along with the specific references and combinations Defendants intend to use to support those defenses in their post-trial brief.

If the Court would like to discuss this matter further, Amgen is available to discuss at the Court's convenience. Amgen thanks the Court for its consideration and assistance in this matter.

Respectfully submitted,

s/ Charles H. Chevalier
Charles H. Chevalier

cc: all counsel of record (via ECF and Email)

DENIED this 29th day of June, 2021

A handwritten signature in black ink, appearing to read "M. Shipp", written in a cursive, stylized font.

Honorable Michael A. Shipp, U.S.D.J.